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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,708	02/20/2001	Akiko Itai	P20294	4541

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EXAMINER

BORIN, MICHAEL L

ART UNIT

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1631

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/700,708	Applicant(s) Itai et al	
	Examiner Michael Borin	Art Unit 1631	
-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --			
Period for Reply <p>A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.</p> <p> <input checked="" type="checkbox"/> Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. <input type="checkbox"/> If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. <input type="checkbox"/> If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. <input type="checkbox"/> Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). <input type="checkbox"/> Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). </p>			
Status <p>1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>Dec 27, 2002</u></p> <p>2a) <input type="checkbox"/> This action is FINAL. 2b) <input checked="" type="checkbox"/> This action is non-final.</p> <p>3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11; 453 O.G. 213.</p>			
Disposition of Claims <p>4) <input checked="" type="checkbox"/> Claim(s) <u>1-8</u> is/are pending in the application.</p> <p>4a) Of the above, claim(s) <u>1-4</u> is/are withdrawn from consideration.</p> <p>5) <input type="checkbox"/> Claim(s) _____ is/are allowed.</p> <p>6) <input checked="" type="checkbox"/> Claim(s) <u>5-8</u> is/are rejected.</p> <p>7) <input type="checkbox"/> Claim(s) _____ is/are objected to.</p> <p>8) <input type="checkbox"/> Claims _____ are subject to restriction and/or election requirement.</p>			
Application Papers <p>9) <input type="checkbox"/> The specification is objected to by the Examiner.</p> <p>10) <input type="checkbox"/> The drawing(s) filed on _____ is/are a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).</p> <p>11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action.</p> <p>12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.</p>			
Priority under 35 U.S.C. §§ 119 and 120 <p>13) <input type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) <input type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of: 1. <input type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</p> <p>*See the attached detailed Office action for a list of the certified copies not received.</p>			
<p>14) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.</p> <p>15) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.</p>			
Attachment(s) <p>1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). <u>5, 6, 14</u></p> <p>4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>6) <input type="checkbox"/> Other: _____</p>			

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DETAILED ACTION

Status of Claims

1. Response to restriction requirement filed 12/27/2002 is acknowledged. Applicant elected, with traverse, Group II, claims 5-8. As explained in the previous Office action, Group I is not the contribution over the prior art because it is suggested by a plurality of references describing protein databases containing functional information, for example, US Patent 6,023,659. Per applicant's request, a copy of said US patent is enclosed and it is listed on form PTO-892. Similarly, database comprising both amino acid sequence and importance regarding biological functions is described in Chen et al (copy enclosed). Claims 1-4 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected groups.

Title, Abstract

2. The title and abstract of the invention are not descriptive. The title and abstract do not reflect the elected invention which is drawn to method of preparing an alignment of a protein. A new title and abstract are required which are clearly indicative of the invention to which the elected claims are directed.

Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 5-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is applied for the following reasons:

- A. Claim 5 recites limitations of claim 1 (database according to claim 1) which is not under consideration. Please include all claimed limitations in claim 5.
- B. Claim 5, line 4: it is not clear, whether phrase "each constituent amino acid" relates to known protein or unknown polypeptide;
- C. Claim 5, line 5: Not clear whether phrase "under consideration" relates to "each amino acid" (i.e., amino acid under consideration) or ""importance score" (i.e., calculating homology ... under consideration of the importance score). If the former is correct, it is not clear how "importance score..." effects calculation of homology score to the coincidence of each amino acid under consideration.

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D. Claim 5, line 5: The term "importance score " is not defined by the claim. The specification, although providing particular examples, does not provide a standard for ascertaining what constitutes an "importance score", and one of ordinary skills in the art would not be reasonably apprised of the scope of the invention.

E. Claim 5, line 7, and claim 6: The term "importance is high" is not clear. Is "importance score", rather than "importance" meant?

F. Claim 6: The claim addresses method further comprising "searching correspondences" for groups of two or more continuous amino acid residues. Does it mean that searching for groups of two or more continuous amino acid residues is done in addition to calculating of homology based on coincidence of each amino acid under consideration, as claimed in the base claim 5?

G. Claims 6-8: The term "target protein" lacks antecedent basis, as the base claim 5 recites "polypeptide with unknown biological function" instead.

H. Claim 7: The claim recites "final score of homology". It is not clear how such score is different from homology score already calculated according to the base claim 5: No new steps which would alter the homology score are addressed in the claim.

I. Claim 8: meaning of predicting of homology with regard to biological function, recited in the claim is not clear: homology is based on structure, rather than on

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function of proteins. Further, it is not clear which method sep leads on the prediction of the most homologous protein.

Claim Rejections - 35 USC § 102 and 103.

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the

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examiner to consider the applicability of 35 U.S.C. 103[©] and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-8 are rejected under 35 U.S.C. 102(b) as anticipated by Chen et al. (Genome Informatics Series, 1998, vol. 9, p. 102-111).

The instant claims are drawn to method of preparing alignment of proteins with known and unknown biological functions, comprising calculating homology score with consideration of an importance score for the appearance of a biological function for the known protein.

Chen et al. describe database integration software "Kleisly". The software allows to combine structural alignment (e.g., using BLAST) with functional characteristics of known protein (i.e, knowledge of "importance" for a given set of residues). For each region of importance, the referenced method integrates alignment with features of the known protein that align well with the query protein. As a further refinement, each group of hits to known proteins is sorted by percentage sequence identity. As a result, the method of Chen allows to obtain protein alignment which, using language of instant claims, represents homology of sites where importance is high.

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It is the Examiners position that all the elements of Applicant's invention are instantly disclosed by the teaching of the reference cited above.

Conclusion.

5. No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

February 28, 2003

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

mlb

